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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,436	08/21/2003	Martin Gleave	UBC.P-030	9171
21121	7590	01/09/2006	EXAMINER	
OPPEDAHL AND LARSON LLP P O BOX 5068 DILLON, CO 80435-5068			CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/646,436

Applicant(s)

GLEAVE ET AL.

Examiner

Kimberly Chong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 10-14, 20, 21, 23, 29 and 31-34 is/are pending in the application.
- 4a) Of the above claim(s) 20, 21, 23, 29, 32 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10-13 is/are rejected.
- 7) ☐ Claim(s) 4, 14, 31 and 33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed 10/10/2005 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 07/22/2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 10/10/2005, claims 1-4, 10-14, 31 and 33 are currently under examination.

### ***Priority***

Applicant's argue that with amendments file 10/10/2005, all claims are now entitled to the claim for domestic priority under 35 U.S.C. 119(e). The Provisional application 60/405,193 filed on 08/21/2002 provide adequate support for claims 1-3 and 12-13. However, the Provisional applications 60/405,193, 60/408,152 and 60/472,387 upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for claims 4, 10-11, 14, 31 and 33 of this application.

Claims 10-11 are drawn to a pharmaceutical composition comprising a RNA molecule less than 49 nucleotides in length. Claims 4, 14, 31 and 33 are drawn to RNA molecule comprising a sequence having SEQ ID NO. 10.

The Provisional applications 60/405,193, 60/408,152 and 60/472,387 disclose a RNA molecule 21 to 23 nucleotides in length. The above-mentioned applications fail to provide adequate support for RNA molecules less than 49 nucleotides in range but greater than 23 and further the applications fail to provide support for an RNA molecule less 19 nucleotides in length. Further, the Provisional applications 60/405,193, 60/408,152 and 60/472,387 fail to provide adequate support for an RNA molecule comprising a sequence having SEQ ID NO. 10. If applicant feels there is adequate support then applicant must point out, with particularity, where such support can be found.

Therefore, claims 4, 10-11, 14, 31 and 33 are given a priority date of 08/21/2003, the filing date of the instant application. Claims 1-3 and 12-13 are given a priority date of 08/21/2002, the filing date of Provisional application 60/405,193.

### *Claim Objections*

Claims 4, 14, 31 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if applicant cancels non-elected subject matter and the claims are rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Monia et al.

(US Patent No. 6,383,808).

Claims 10-11 are drawn to a pharmaceutical composition wherein the pharmaceutically acceptable carrier is a sterile injectable solution and comprising an RNA molecule having a length of less than 49 bases targeted to a gene that encodes clusterin.

Monia et al. teach an oligonucleotide that can be RNA or a ribozyme (see column 6, lines 37-63) that is targeted to clusterin mRNA (see Table 1). Monia et al. further teach the compounds are preferably from 12 to 30 nucleotides in length (see column 6, lines 54-59). Monia et al. teach a pharmaceutical composition comprising an RNA molecule and wherein the pharmaceutically acceptable carrier is a sterile injectable solution (see column 14, lines 4-10).

Thus, Monia et al. anticipates claims 10-11 of the instant application.

### ***Response to Applicant's Arguments***

The rejection of record of claims 1-2 and 12 under 35 U.S.C. 102(b) as being anticipated by Monia et al. (US Patent No. 6,383,808) is withdrawn in response to Applicant's amendments filed 10/10/2005.

The rejection of record of claims 1-3 and 10-13 under 35 U.S.C. 102(e) as being anticipated by Monia et al. (US Patent No. 6,383,808) is maintained.

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Applicant's arguments filed 10/10/2005 have been fully considered but are not persuasive. Applicant argues that the RNA sequence disclosed in Monia et al. does not "mediate degradation or block translation of mRNA that is the transcriptional product of a target gene."

Monia et al. disclose in column 4 that the RNA sequence interferes with all vital functions of RNA, such as "...translation of protein from the RNA." Monia et al. disclose that such interference of the target gene means a decrease (inhibition) in the expression of the clusterin target gene. Contrary to Applicant's arguments, binding of the RNA sequence targeted to the clusterin target gene will "mediate degradation" of the gene.

Applicant further argues that because of amendments filed 10/10/2005, the claims are now entitled to a claim for priority and accordingly Monia et al. (U.S. Patent No. 6,383,808) is not a reference under 35 U.S.C. 102(e). As stated above, claims 10-11 are given a priority date of 08/21/2003, the filing date of the instant application and claims 1-3 and 12-13 are given a priority date of 08/21/2002, the filing date of Provisional application 60/405,193. Monia et al. (U.S. Patent No. 6,383,808) has an effective filing date of September 11, 2000 and is therefore prior art under 35 U.S.C. 102(e).

Therefore, the rejection of record of claims 1-3 and 10-13 under 35 U.S.C. 102(e) as being anticipated by Monia et al. (US Patent No. 6,383,808) is maintained.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### *Conclusion*

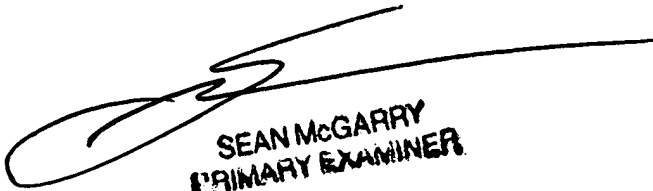
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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Kimberly Chong  
Examiner  
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